

Procter & Gamble

PROCTER & GAMBLE SUBMISSION

TO

ANTIGINGIVITIS/ANTIPLAQUE ANPR

DOCKET NO. 81N-033P

NOVEMBER 21, 2003

81N-033P

C 14

November 21, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re:Docket No. 81N-033P, Oral Health Care
Drug Products for Over-the-Counter Human
Use; Antigingivitis/Antiplaque Drug
Products; Establishment of a Monograph;
Proposed Rules

Dear Sir or Madam:


The Procter & Gamble Company, a leader in dental and oral care products, respectfully submits these comments and new data in response to the Advance Notice of Proposed Rulemaking on OTC Antigingivitis/Antiplaque Drug Products published May 29, 2003 in the *Federal Register* (FR Doc03-12783). As the manufacturer of the Crest[®] and Scope[®] family of oral care products, Procter & Gamble has a significant interest in the ongoing development of this monograph.

Procter & Gamble appreciates the opportunity to provide input to the establishment of the OTC Antigingivitis/Antiplaque Monograph. During the call-for-data period and the Subcommittee deliberations, Procter & Gamble submitted to the docket and presented to the Subcommittee a substantial amount of information related to two active ingredients under consideration as antigingivitis/antiplaque agents, stannous fluoride and cetylpyridinium chloride. Both of these active ingredients were subsequently recommended to Category I status by the Plaque Subcommittee. This submission augments the previous information supporting stannous fluoride and cetylpyridinium chloride and provides our recommendations for the Agency to consider in the development of the OTC Tentative Final Monograph for Antigingivitis/Antiplaque Drug Products.

Our comments are organized into five main sections within this document:

1. Executive Summary of Procter & Gamble recommendations
2. Responses to questions/comments raised by the Agency in the preamble to the ANPR
3. New Data and Comments on Stannous Fluoride (SnF_2)
4. New Data and Comments on Cetylpyridinium Chloride (CPC)
5. General Monograph Considerations and Labeling

Respectfully submitted on behalf of The Procter & Gamble Company



Todd J. Banks, BSc., R.Ph.
Oral Care Regulatory Affairs Manager
The Procter & Gamble Company
P.O. Box 8006
8700 Mason-Montgomery Road
Mason, OH 45040-8006
Email: banks.tj@pg.com